PATENT COOPERATION TREATY

PCT

TRANSLATION INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference GRA3142PCT		FOR FURTHER A	CTION	See Form PCT/IPEA/416				
International application No.		International filing dat	e (day/month/year)	Priority date (day/month/year)				
PCT/	EP2004/014146	13.12.200	4	12.12.2003				
International Patent Classification (IPC) or national classification and IPC								
A61K9/70								
Applicant								
LTS LOHMANN THERAPIE-SYSTEME AG								
 This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 								
	This REPORT consists of a tota		sheets, including	g this cover sheet.				
	a. (sent to the applicant and to the International Bureau) a total of 4 sheets, as follows:							
	sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or							
	sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).							
	sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental							
	Box.							
	b (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s))							
	, containing a sequence listing and/or tables							
		puter readable form only, as ninistrative Instructions).	indicated in the Supple.	mental Box Relating to Sequence Listing (see				
4.	This report contains indications	relating to the following item	ns:					
	Box No. I Basis of the report							
[Box No. II Priority							
[Box No. III Non-e	stablishment of opinion with	regard to novelty, invent	ive step and industrial applicability				
[Box No. IV Lack of unity of invention							
	BON IVO. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement						
[Box No. VI Certain	Certain documents cited						
[Box No. VII Certain	ertain defects in the international application						
[Box No. VIII Certain	VIII Certain observations on the international application						
Date of submission of the demand			Date of completion of this report					
			<i>k</i>	•				
Name and mailing address of the IPEA/EP			Authorized officer					
_								
Facsimile No.			Telephone No.					

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/014146

Box	No. I	. I Basis of the report		
1.		ith regard to the language , this report is based on the international applicated under this item.	olication in the language in w	which it was filed, unless otherwise
		This report is based on translations from the original language into which is the language of a translation furnished for the purposes o international search (Rule 12.3 and 23.1(b)) publication of the international application (Rule 12.4) international preliminary examination (Rule 55.2 and/or 55.	f:	,
2.	recei	ith regard to the elements of the international application, this report ceiving Office in response to an invitation under Article 14 are refers s report): the international application as originally filed/furnished the description:		
		pages* 4-27 pages* 1-3 rece	ived by this Authority on	as originally filed/furnished 14.09.2005 with letter of 12.09.2005
		pages* rece	ived by this Authority on	
	\boxtimes	the claims:		
		nos. 2–15		as originally filed/furnished
		nos.*		with any statement) under Article 19
		nos.* 1 rece		14.09.2005 with letter
		nos.* rece		
	\boxtimes	the drawings:	, <u> </u>	
		sheets 1/3-3/3		as originally filed/furnished
		sheets* rece		
		1	-	
	H	a sequence listing and/or any related table(s) – see Supplemental I	Box Relating to Sequence Lis	sting.
3.		The amendments have resulted in the cancellation of:		
		the description, pages		
		the claims, nos.		
		the drawings, sheets/figs		
		the sequence listing (specify):		
		any table(s) related to sequence listing (specify):		
4.	\boxtimes	This report has been established as if (some of) the amendments they have been considered to go beyond the disclosure as filed, as		
		the description, pages 1-3		<u> </u>
		the claims, nos. 1		·
		the drawings, sheets/figs		
		the sequence listing (specify):		
		any table(s) related to sequence listing (specify):		
*	If ite	item 4 applies, some or all of those sheets may be marked "supersede		

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/014146

YES
NO NO
YES
NO
YES
NO

- 2. Citations and explanations (Rule 70.7)
 - 1. See supplemental sheet: continuation of Box I.
 - 2. In these proceedings, reference is made to documents cited in the international search report. The documents are numbered D1 to D5 according to the order in which they are cited in the search report. The cited passages of the respective documents, in particular, will be taken into account.
 - 3. Novelty (PCT Article 33(2))

 The subject matter of claims 1 to 15 is considered to be novel over the cited prior art.

 Claim 1 differs from the disclosure in D1 to D3 by the addition of glycerol as a plasticizer.
 - 4. Inventive step (PCT Article 33(3))

 The problem addressed by the application is that of providing a film-forming administration form for the topical administration of at least one active substance, which administration form is easier to use, in particular, with regard to improved application thereof.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

This problem is solved by a film-forming administration form according to claim 1 comprising glycerol as a plasticizer. Film-forming administration forms comprising cross-linked hydrophilic polymers, in particular, HPMC crosslinked with tannin, are already known from the prior art (D1 to D3). D1 to D3 do not, however, disclose the addition of glycerol as a plasticizer.

However, a person skilled in the art is familiar with glycerol as an additive functioning as a plasticizer to polysaccharide films, in particular, HPMC films, from D4 and D5.

It seems likely that a person skilled in the art would have taken in particular D5 into account because this document deals in general with the mechanical and water vapor transmission properties of polysaccharide films.

D5 (page 1203, right-hand column, lines 43-46) describes that HPMC films are effectively plasticized with glycerol and that with 30% glycerol, the puncture strength remains unchanged. The addition of 30% glycerol to HPMC films is also verified at other places in the document (see, for example, table 2, figure 3)

It must therefore be assumed that a person skilled in the art is clearly prompted by D5 to use glycerol as a plasticizer and in amounts greater

International application No.
PCT/EP2004/014146

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement than 20%. An inventive step under PCT Article 33(3) therefore cannot be recognized for the subject matter of claims 1 to 15. 5. Clarity (PCT Article 6) It appears that claim 1 relates to 20% by weight of glycerol, and claim 2, which is dependent on claim 1, relates to 20 to 60% by weight of glycerol. The scope of protection of claim 2 is therefore broader than that of claim 1. It seems appropriate to reverse the order of the claims so that the narrower claim is dependent on the broader claim.

PCT/EP2004/014146

Supplemental Box

In case the space in any of the preceding boxes is not sufficient. Continuation of: $Box\ I$

The amendments submitted with the letter of 12 September 2005 cannot be considered obvious errors within the meaning of PCT Rule 91. It is not obvious or immediately discernible to a person skilled in the art that nothing else other than the proposed rectifications could have been intended. Another range, such as 20-70%, could also have been intended.

The proposed rectifications are therefore considered to be modifications within the meaning of PCT Article 34(2b) which go beyond the disclosure in the international application as filed because there is no basis in the application documents for the modification to $\geq 20\%$ by weight.

This report is therefore based on the originally submitted documents (claims and description).